U.S.S.N. 09/933,548
Filed: August 20, 2001
AMENDMENT AND RESPONSE TO OFFICE ACTION

In the Claims

1. (original) A method of determining the susceptibility of a human patient to prostate cancer comprising the steps of (i) obtaining a sample containing nucleic acid and/or protein from prostate cells of the patient; and (ii) determining whether the sample contains ~~a level of~~ Pax 2 nucleic acid or protein associated with prostate cancer.

2. (presently amended; one time) A method of diagnosing prostate cancer in a human patient comprising the steps of:

(i) obtaining a sample containing ~~nucleic acid and/or protein~~ mRNA from a test sample of prostate cells ~~of~~ from the patient; and

(ii) ~~determining whether the sample contains a level of Pax 2 nucleic acid or protein associated with prostate cancer.~~ comparing the amount of any Pax 2 mRNA detected in the test sample with the amount of any Pax 2 mRNA detected in a control sample known to contain non-cancerous or non-metastatic cells.

3. (presently amended; one time) A method of ~~predicting the relative prospects of a particular outcome~~ identifying the presence and metastatic potential of prostate cancer in a human patient comprising the steps of:

(i) obtaining a sample containing ~~nucleic acid and/or protein~~ mRNA from a test sample of prostate cells ~~of~~ from the patient; and

(ii) ~~determining whether the sample contains a level of Pax 2 nucleic acid or protein associated with prostate cancer.~~ comparing the amount of any Pax 2 mRNA detected in the test

sample with the amount of any Pax 2 mRNA detected in a control sample known to contain non-cancerous or non-metastatic cells.

4. (previously amended; one time) A method according to any of claims 1, 2 or 3 wherein the cancer is invasive.

5. (previously amended; one time) A method according to any of claims 1, 2, or 3 wherein the sample contains nucleic acid and the level of Pax 2 nucleic acid is measured by contacting the nucleic acid with a nucleic acid which hybridises selectively to Pax 2 nucleic acid.

6. (original) A method according to claim 5 wherein the sample contains mRNA and the nucleic acid selectively hybridises to Pax 2 mRNA.

7. (previously amended; one time) A method according to claim 5 ~~or 6~~ wherein the nucleic acid which hybridises is detectably labelled.

8. (previously amended; one time) A method according to claim 5 wherein the nucleic acid which selectively hybridises is detectably labelled.

9. (previously amended; one time) A method according to claim 5 wherein the nucleic acid which selectively hybridises is suitable for use in a nucleic acid amplification reaction.

10. (previously amended; two times) A method according to any of claims 1, 2 or 3 wherein the sample contains protein and the level of Pax 2 protein is measured.

11. (original) A method according to claim 10 wherein the level of protein is measured by contacting the protein with a molecule which selectively binds to Pax 2 protein.

12. (original) A method according to claim 11 wherein the selective binding molecule is an antibody or fragment or derivative thereof or an antibody-like molecule.

13. (original) A method according to claim 11 or 12 wherein the selective binding molecule comprises a detectable label.

14. (original) A method according to claim 10 wherein the level of Pax 2 is measured by selectively assaying its activity in the sample.

15. (previously amended; one time) A method according to any of claims 1, 2 or 3 wherein the sample is a sample of the tissue in which prostate cancer is suspected or in which prostate cancer may be or has been found, or contains cells from said tissue.

16. (original) A method according to claim 15 wherein the sample is any one of urine, semen, blood or lymphatic circulation.

17. (previously amended; one time) A method of diagnosing prostate cancer comprising administering an agent which is capable of use in determining the level of Pax 2 protein or nucleic acid in a sample in the manufacture of a reagent for diagnosing prostate cancer.

18. (previously amended; one time) The method of claim 17 wherein the agent is a nucleic acid which selectively hybridises to Pax 2 nucleic acid.

19. (previously amended; one time) The method of claim 18 wherein the agent is a molecule which selectively binds to Pax 2 protein.

20. (previously amended; one time) The method of claim 19 wherein the agent is useful in selectively assaying the activity of Pax 2 protein.

Claims 21 and 22 were previously canceled.

23. (presently amended; two times) A kit for diagnosing prostate cancer comprising an agent which is capable of use in determining ~~the~~ a level of Pax 2 protein or nucleic acid in a

sample and a control sample wherein the control sample may be a negative control not comprising a detectable amount of Pax 2 nucleic acid or protein, or it may be a positive control comprising a detectable amount of Pax 2 nucleic acid or protein.

24. (original) A method of treating prostate cancer comprising the step of administering to the patient an agent which selectively prevents the function of Pax 2.

25. (original) A method according to claim 24 wherein the agent prevents the expression of Pax 2.

26. (original) A method according to claim 24 wherein the agent inhibits the activity of Pax 2.

27. (original) A method according to claim 26 wherein the agent is an antisense molecule.

28. (original) A method according to claim 26 wherein the agent is a ribozyme.

29. (previously amended; one time) A method of treating prostate cancer comprising administering an agent which selectively prevents the function of Pax2.

30. (original) A genetic construct a nucleic acid encoding a molecule capable of preventing the function of Pax 2 expressed in a prostate cell.

31. (original) A genetic construct according to claim 30 adapted for delivery to a human prostate cell.

32. (original) A genetic construct according to claim 31 wherein the adaptation allows delivery to a prostate cancer cell.

33. (previously amended; one time) A genetic construct according to claim 31 comprising means to selectively deliver the nucleic acid to a prostate cancer cell.

34. (previously amended; one time) A genetic construct according to claim 30 comprising means to selectively express the nucleic acid encoding a molecule in a prostate cancer cell.

Claim 35 was previously canceled.

36. (previously amended; one time) A pharmaceutical composition comprising a genetic construct comprising a nucleic acid encoding a molecule capable of preventing the function of Pax 2 expressed in a prostate cell and a pharmaceutically acceptable carrier.

37. (previously amended; one time) The method of claim 2 wherein the step of determining whether the sample contains a level of Pax 2 protein associated with prostate cancer is carried out using western blotting.

Claim 38 was previously canceled.

39. (new) A method according to claim 2 wherein no Pax 2 mRNA is detectable in the sample of non-cancerous or non-metastatic cells.

40. (new) A method according to claim 2 wherein the amount of detectable Pax 2 mRNA is at least 1.5 fold higher than the amount of detectable Pax 2 mRNA in the sample of non-cancerous or non-metastatic cells.

41. (new) A method according to claim 3 wherein no Pax 2 mRNA is detectable in the sample of non-cancerous or non-metastatic cells.

42. (new) A method according to claim 3 wherein the amount of detectable Pax 2 mRNA is at least 1.5 fold higher than the amount of detectable Pax 2 mRNA in the sample of non-cancerous or non-metastic cells.

43. (new) A method according to any one of claims 2, 3, 39, 40, 41, or 42, wherein the cancer is invasive.

44. (new) A method according to any one of claims 2, 3, 39, 40, 41, or 42, wherein the sample contains mRNA and the amount of Pax 2 mRNA is measured by contacting the mRNA with a nucleic acid which hybridizes selectively to Pax 2 mRNA.

45. (new) A method according to claim 44 wherein the nucleic acid which hybridizes is detectably labeled.

46. (new) A method according to claim 44 wherein the nucleic acid which selectively hybridizes is detectably labeled.

47. (new) A method according to claim 44 wherein the nucleic acid which selectively hybridizes is suitable for use in a nucleic acid amplification reaction.

48. (new) A method according to any one of claims 2, 3, 39, 40, 41, or 42, wherein the sample is a sample of the tissue in which prostate cancer is suspected or in which prostate cancer may be or has been found, or contains cells from said tissue.

49. (new) A method according to claim 48 wherein the sample is selected from the group consisting of urine, semen, blood, and lymphatic circulation.